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February 15, 2008

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From: Brent P. Ray

Direct Telephone No.: (312) 269-1521

JP No.: JP006602

CAM No.: 636570-600001

Send copies to:

Number of pages (including this page): 9

Re: In re: U.S. Patent No. 4,994,078

Issued: February 19, 1991

Inventor: Robert K. Jarvik

For: INTRAVENTRICULAR ARTIFICIAL HEARTS AND METHODS OF THEIR  
SURGICAL IMPLANTATION AND USE

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re:** U.S. Patent No. 4,994,078      **Attorney Docket No.:** 012373-001-999  
**Issued:** February 19, 1991      **CAM No.** 636570-600001

**Inventors:** Robert K. Jarvik

**For:** INTRAVENTRICULAR  
ARTIFICIAL HEARTS  
AND METHODS OF  
THEIR SURGICAL  
IMPLANTATION AND  
USE

**MAIL STOP PATENT EXTENSION**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUBMISSION UNDER 37 C.F.R. § 1.740(a)(13)**

Sir or Madame:

Pursuant to 37 C.F.R. § 1.740(a)(13), Jarvik Heart, Inc., through the undersigned, submits (1) a January 30, 2008 cover letter enclosing Module 1: System Engineering for PMA Shell Number M070017 to the U.S. Food and Drug Administration ("FDA"), and (2) Federal Express proof of delivery of Module 1 to the FDA on February 1, 2008.

No fee is believed due for this submission. Should any fee(s) be due at this time, please charge such fee(s) to Jones Day Deposit Acct. No. 503013.

Respectfully submitted,

Date: February 15, 2008

*F. Dominic Cerrito*      *by: Brent H. Kang* (Reg. No. 54,390)  
F. Dominic Cerrito      (Reg. No. 38,100)  
**JONES DAY**  
222 East 41st Street  
New York, New York 10017  
(212) 326-3939



Mary Blinder, MD  
Director of Medical Affairs

PMA Document Mail Center (HFZ-401) Center for Devices & Radiological Health Food and Drug Administration 9200 Corporate Boulevard Rockville, MD 20850	PMA Shell Number: M070017 Module 1: System Engineering  Sponsor, Manufacturer and Applicant: Jarvik Heart, Inc. 333 West 52 <sup>nd</sup> Street New York, New York 10019 212-397-3911 Fax 212-397-3919
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January 30, 2008

Dear Dr. Patel,

Enclosed are three (3) hardcopies of PMA Shell Number M070017, Module 1: System Engineering for the Jarvik 2000 Heart Assist System. In addition, per the instructions accessed at <http://www.fda.gov/cdrh/electsub.html>, two (2) electronic copies are provided with this submission and both copies are an exact duplicate of the original paper submission.

In addition, we are submitting the following 3 documents related to fees for your records even though we do not believe these documents are mandatory:

Eligibility for Small Business Qualification  
Facility Registration  
Draft Medical Device User Fee Cover Letter

Please contact me at (212) 397-3911 ext. 30 or [mblinder@jarvikheart.com](mailto:mblinder@jarvikheart.com) if you have any questions.

Sincerely,

A handwritten signature in cursive script that reads "Mary Blinder, MD".

Mary Blinder, MD

333 West 52<sup>nd</sup> Street, New York NY 10019-6238 Ph: (212) 397-3911 x.30 Fax: (212) 397-3919 [mblinder@jarvikheart.com](mailto:mblinder@jarvikheart.com)

Mary Blinder, M.D.

---

From: Pamela DeLaGrange [pdelagrange@jarvikheart.com]  
Sent: Friday, February 01, 2008 11:28 AM  
To: Dr Jarvik; 'Stuart McConchie'; 'Mary Blinder, M.D.'; 'Janine Lynch'; 'Kamal Gandhi'  
Subject: FW: FedEx MPS Shipment 798864320906 Delivered

Attached is your copy of the delivery verification of the PMA Submittal to the FDA

Pamela

-----Original Message-----

From: TrackingUpdates@fedex.com [mailto:TrackingUpdates@fedex.com]  
Sent: Friday, February 01, 2008 11:13 AM  
To: pdelagrange@jarvikheart.com  
Subject: FedEx MPS Shipment 798864320906 Delivered

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This tracking update has been requested by:

Company Name:	Jarvik Heart, Inc.
Name:	Pamela DeLaGrange.
E-mail:	pdelagrange@jarvikheart.com

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Our records indicate that the following MPS shipment has been delivered:

Reference:	PMA #M070017 Module 1
Ship (P/U) date:	Jan 31, 2008
Delivery date:	Feb 1, 2008 10:24 AM
Sign for by:	M.BENJAMIN
Service type:	FedEx Priority Overnight
Packaging type:	Your Packaging
Tracking number:	<u>790929393305</u>
Delivered to:	Mailroom
Weight:	50.00 lb.
Special handling/Services:	Deliver Weekday

Tracking number:	<u>798364560110</u>
Delivered to:	Mailroom
Weight:	50.00 lb.
Special handling/Services:	Deliver Weekday

Master tracking number:	<u>798864320906</u>
Delivered to:	Mailroom
Weight:	50.00 lb.
Special handling/Services:	Deliver Weekday

Shipper Information

Recipient Information

2/1/2008

From: Origin ID: QNYA (212397-3911)  
 Pamela DeLoGrange  
 Janyk Mezt, Inc.  
 333 West 52nd Street  
 Room 700  
 New York, NY 10019



Ship Date: 3/1/2008  
 Act Wgt: 50 LB  
 System#: 1606634/NET0011  
 Account#: 5

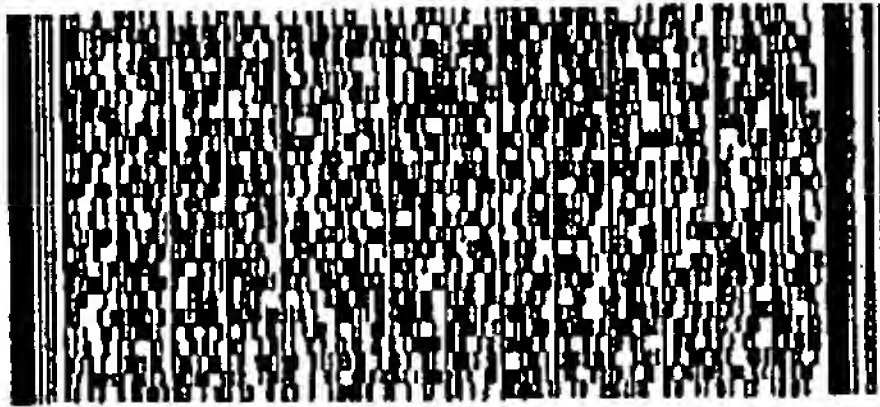
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Delivery Address Bar Code



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 Invoice #  
 PO #  
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 ROCKVILLE, MD 208503229

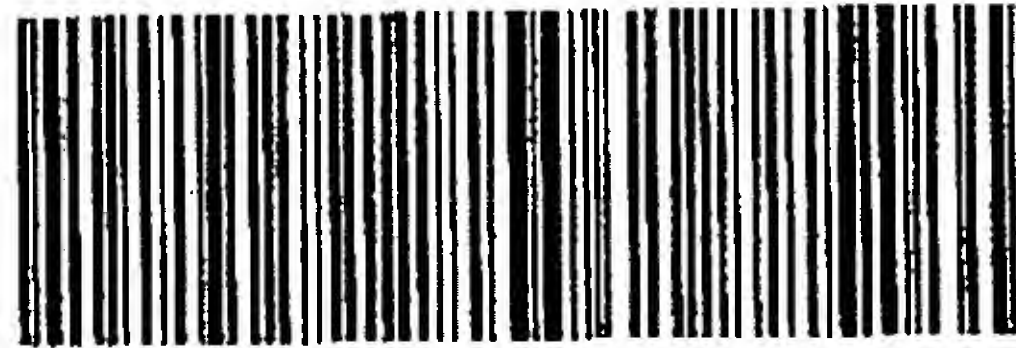


1/3  
 TRK# 7988 6432 0906  
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From: Origin ID: QNYA (212)397-3911  
 Pamela DeLaGrange  
 Jarvis Health, Inc.  
 333 West 52nd Street  
 Room 700  
 New York, NY 10019



Ship Date: 31 JAN 08  
 Act Wgt: 50 LB  
 System#: 1609634/INET8011  
 Account#: S

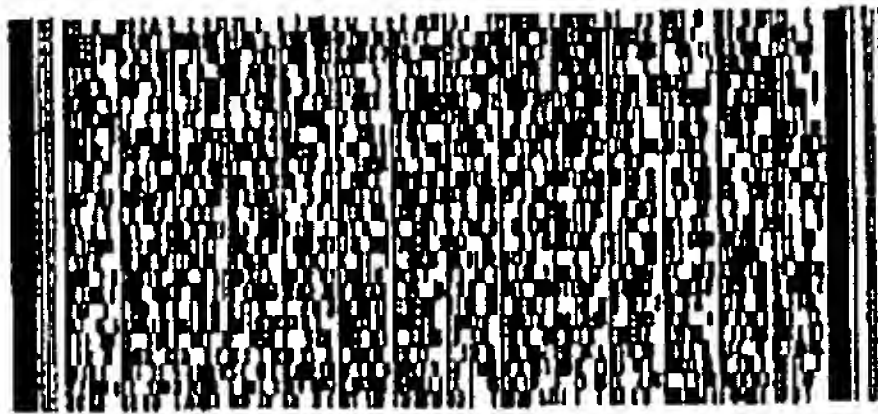
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Delivery Address Bar Code



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 Invoice #  
 PO #  
 Dept #

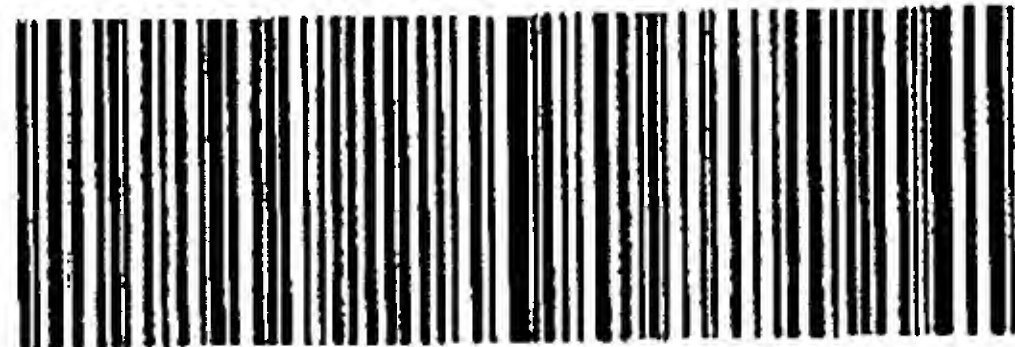
SHIP TO: 212 397 3911 BILL SENDER  
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 ROCKVILLE, MD 208503229



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 Mstr# 7988 6432 0906 0201

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From: Origin ID: QNYA (212)397-3911  
 Pamela DeLaGrange  
 Jank Health, Inc.  
 333 West 52nd Street  
 Room 700  
 New York, NY 10019



Ship Date: 31JAN08  
 ActWgt: 50 LB  
 System: 1609634/NET8011  
 Account: S \*\*\*\*\*

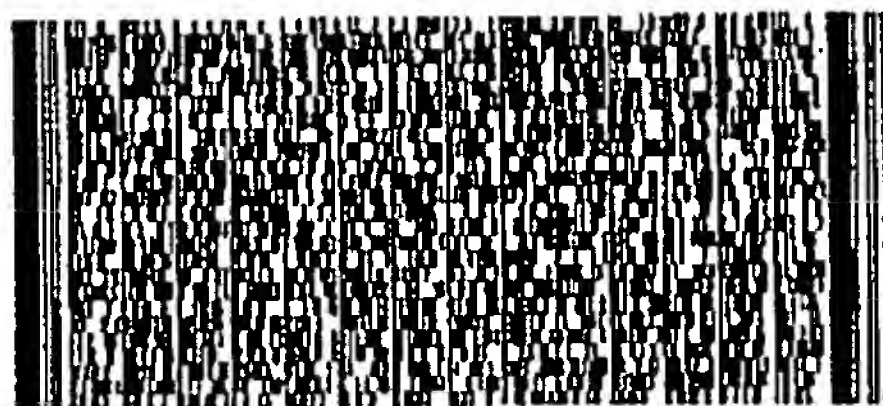
Dimmed: 20 X 15 X 15 IN

Delivery Address Bar Code



Ref # PMA#M070017 Module 1  
 Invoice #  
 PO #  
 Dept #

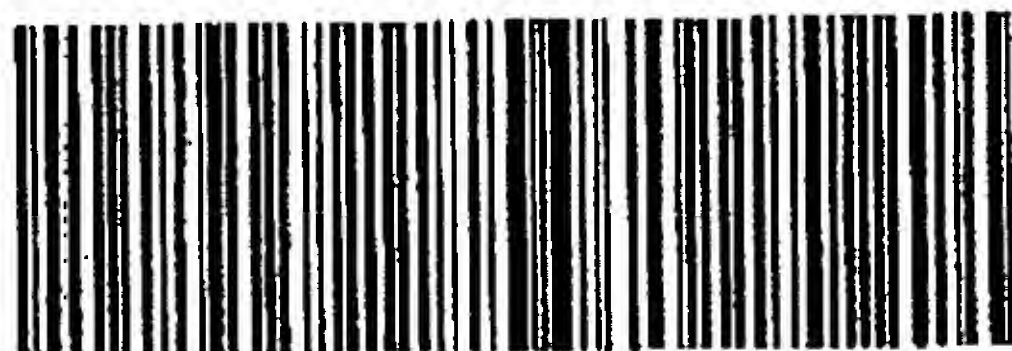
SHIP TO: 212 397 3911 BILL SENDER  
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MPS# 3/3 FRI - 01FEB A2  
 0283 7983 6456 0110 PRIORITY OVERNIGHT  
 Mstr# 7988 6432 0906 0201

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**Pamela DeLaGrange**

**From:** TrackingUpdates@fedex.com  
**Sent:** Friday, February 01, 2008 11:13 AM  
**To:** pdelagrangear@jarvikheart.com  
**Subject:** FedEx MPS Shipment 798864320906 Delivered

This tracking update has been requested by:

**Company Name:** Jarvik Heart, Inc.  
**Name:** Pamela DeLaGrange  
**E-mail:** pdelagrangear@jarvikheart.com

Our records indicate that the following MPS shipment has been delivered:

**Reference:** PMA #M070017 Module 1  
**Ship (P/U) date:** Jan 31, 2008  
**Delivery date:** Feb 1, 2008 10:24 AM  
**Sign for by:** M.BENJAMIN  
**Service type:** FedEx Priority Overnight  
**Packaging type:** Your Packaging

**Tracking number:** 790929393305  
**Delivered to:** Mailroom  
**Weight:** 50.00 lb.  
**Special handling/Services:** Deliver Weekday  
**Tracking number:** 798364560110  
**Delivered to:** Mailroom  
**Weight:** 50.00 lb.  
**Special handling/Services:** Deliver Weekday  
**Master tracking number:** 798864320906  
**Delivered to:** Mailroom  
**Weight:** 50.00 lb.  
**Special handling/Services:** Deliver Weekday

**Shipper Information**  
Pamela DeLaGrange  
Jarvik Heart, Inc.  
333 West 52nd Street; Room 700  
New York  
US  
10019

**Recipient Information**  
Food and Drug Admin.  
PMA Document Mail Ctr(HFZ-401)  
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